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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,237	03/20/2000	Seth D. Rose	344-P-16-USA	9691

7590 04/23/2002

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

8

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/509,237

Applicant(s)

ROSE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Examiner acknowledges receipt of paper number 6 filed 01/16/02.

#### ***Claim Rejections - 35 USC § 112***

##### ***Specification***

1. This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-6 recite "other than..." that excludes that which is not applicants' invention but the claims fail to point out and distinctly claim that which is applicants' invention. Applicants may recite their invention and then go on to exclude with a proviso that which is not the invention

"Other" in claims 1-6 is indefinite because it is not clear what is included and excluded by the term "other"

Claim 4 is indefinite because it is not clear what the interaction agent is interacting with in part (c) of claim 4.

What is included or excluded in "any" in part 5(d), line 2 and part 6(d), line 2 and "any other" in part 4(e), line 1?

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The claims have generally excluded what is not the invention but failed to recite or define what the invention is.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-6 remain rejected under 35 U.S.C. 102(b) as being anticipated by Blank (US 4,533,540).

Applicants agree that Blank is preoccupied with controlling the dosage of nitroglycerine and that Blank's composition is administered via ointment, gel or film in a Vaseline or lanolin base. Applicants further agree that Blank discloses a copolymer of polyvinylpyrrolidone and nitroglycerine or other vasodilator for the sustained delivery of the vasodilator to prevent the risk of heart attack caused by a drop in the dosage of vasodilator. Applicants also agree that applicants' invention is insoluble in body fluids, modified polymer as defined in the specification and that a linker and hydrophobic group is transferred from an interaction agent to the polymer to form an interaction product.

6. Applicant's arguments filed 01/16/02 have been fully considered but they are not persuasive. Applicants' method is mere application of a polymer solution to treatment site, and the polymerization of the polymer at the site of application after the solvent evaporates from the application site to form the polymer. Thus naturally, once the polymer is formed, it no longer would be soluble in the body fluids. A copolymer or homopolymer or heteropolymer that

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comprises one or more monomer units is a modified polymer according to the interpretation of the definition for modified polymer advanced by applicants. Contrary to applicants argument, a copolymer of polyvinylpyrrolidone and nitroglycerine or other vasodilator is a modified polymer. Also, polyvinylpyrrolidone is a polymer of vinylpyrrolidone monomers linked together by a linker. Applicants method claims do not exclude gels or film or cream and specifically the specification defines liquid as a runny liquid, viscous lotion or spreadable self-supporting gel (page 17, lines 7-18 of the specification). Applicants have not claimed transferring hydrophobic group from an interaction agent to the polymer. The claims do not exclude nitroglycerine or other medicaments from the invention because the claims recite comprising. In composition claims it is not critical how the composition is made and the route of administration of the composition.

7. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Mueller et al. (US 4,826,677).

Mueller teaches applying polymer dispersions containing medicines to skin to treat psoriasis. The liquid polymer solution polymerizes in situ to form a film as the solvent evaporates out of the solution or dispersion applied to the skin. The polymeric materials in Mueller are polyethylene, polyurethane, polyvinyl chloride, polyvinyl alcohols, polyvinyl acetate, polymethacrylates or mixtures thereof and methylcelluloses. Including functional groups through copolymerization with appropriate monomers produces cationic or anionic polymers. Urea is simultaneously present either in dissolved form or suspension. See abstract, column 2, line 33-59, column 3, lines 9-44 and claims 1-12. The polymer of Mueller is inherently modified. Mueller anticipates the claims.

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8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marks teaches a composition comprising a gel formulation that contains a therapeutically effective tretinoin, an organic solvent, hydroxyethylcellulose, hydroxypropylcellulose, BHT and BHA and vitamin E (abstract, column 2, lines 57-68 and column 3, lines 1-47). See also examples 2-13 for exemplification of some embodiments.


9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara  
April 20, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600